Federal Y2K Special Data Request
Y2K Readiness Survey of Manufacturers of Essential Medical Supplies[1]

Center for Devices and Radiological Health, FDA

Instructions for Medical Device Manufacturer Y2K Readiness Assessment Survey

(Please Read Before Responding to the Survey)

Introduction - The purpose of this survey is to provide the Food and Drug Administration and the Department of Health and Human Services information with which to evaluate the preparations and readiness of the medical device industry to address the year 2000 (Y2K) and other date-related problems. It will provide summary information that can be used by the government, healthcare facilities and the public in determining what plans and actions to take to assure an uninterrupted supply of essential medical devices (medical and surgical supplies) and to plan any further Y2K-related activities to address needs identified.

Scope of the Survey - The focus of this survey is on those manufacturers that produce essential medical devices that are used and consumed on a recurring basis during the delivery of essential healthcare services and whose availability is critical to the uninterrupted delivery of healthcare and patient welfare. We attempted to limit the addressees for this survey to manufacturers of these types of essential medical supplies, however our capability to do so is imperfect. If you manufacture only durable medical equipment that is not "used up" or consumed on a regular basis and for which a short term interruption in availability would not present significant impact on healthcare delivery, please return the survey with a statement that you produce no consumable medical supplies and a brief description of the type of devices you produce.

The survey requests information about those information technology systems and automated manufacturing systems (including production and process control systems, quality control systems, inventory and distribution systems) that are necessary for the continued production and distribution of safe and effective medical devices. It is intended that a firm's response to the survey include all mission critical systems and processes that are essential for the firm to these tasks. The response to the survey should include information for all mission critical device production facilities under the manufacturer's corporate control, including all product lines, and should include information for all company divisions or subsidiary organizations. Information is only requested regarding production of medical devices and not other products for companies with multiple product lines.

Year 2000 Information and Readiness Disclosure Act - This survey is a "special year 2000 data gathering request" under Section 4(f) of the Year 2000 Information and Readiness Disclosure Act (YIRDA). By responding to this survey, you consent to allowing the identity of your firm and your response to the first section of Question 1, as described in the footnote to Question 1, to be made public. FDA may make this information (the manufacturer and the response to the first section of Question 1) available on its Internet world wide web site as part of the information regarding the Year 2000 date problem and medical devices which includes the Federal Y2K Biomedical Equipment Clearinghouse database. Information submitted in response to all other questions of this survey will be protected under Paragraph (4)(f)(3) of YIRDA. However, aggregate data may be made available to the public.

Definition - The terms "Y2K compliant" or "Y2K compliance" for the purposes of this survey mean that the information technology and automated manufacturing systems utilized in the production of all products can accurately process date/time data (including, but not limited to calculation, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries, and the years 1999 and 2000 and leap year calculations. In simple words, the terms mean that the company's performance and/or functions will not be adversely affected by dates prior to, during and after

---

1 **This Survey is a "special year 2000 data gathering request" under Section 4(f) of the Year 2000 Information and Readiness Disclosure Act. See the footnote for Question 1 of the Survey.**

the Year 2000. It also requires that a company has evaluated external risks that might occur as a result of the Y2K problem and developed appropriate contingency plans.

Expectations for this Survey - We recognize that a simple statement of being Y2K compliant or not with regard to essential business and manufacturing processes at this time is, in many cases, not possible. This can be due to different computer-controlled functions and processes being at different stages of remediation, testing or implementation. It can also be due to different product lines or manufacturing facilities being at different stages of the Y2K preparation process; or to a firm's ultimate capabilities being dependent on external factors. Some of these factors are beyond the control of the firm, therefore requiring adequate contingency plans to address these uncontrollable circumstances. However, the response to the survey questions should reflect the overall status of your corporate-wide Y2K activities for medical devices. Special circumstances may be addressed, if desired, in additional comments that may be necessary to provide an understanding of your specific corporate status. If there are particular product lines or manufacturing facilities whose Y2K compliance status is problematic, especially with regard to situations that could contribute to a shortage of products that are essential medical supplies, please describe these in additional comments. FDA should be informed of any situations in which compliance may not be achieved or adequate contingency arrangements can not be made, and which could lead to interruption in the availability of essential products, so that appropriate actions can be considered to ensure that adequate healthcare delivery continues.

Elements of a Y2K Preparation Program - The phases of a Y2K preparation program identified are modeled on the Year 2000 Conversion Model suggested by the U.S. General Accounting Office in its publication "Year 2000 Computing Crisis; An Assessment Guide" September 1997, GAO/AIMD- 10.1.14. The reader is referred to this GAO report or other sources on Y2K planning for additional information on the contents of a comprehensive Y2K program. An electronic version of the GAO report is available from the GAO's World Wide Web site at the following Internet address: http://www.gao.gov/special.pubs/y2kguide.pdf.

While the GAO guide was designed to provide a framework for assessing the readiness of federal agencies to achieve Y2K compliance, it can be adapted to assess the progress of manufacturing operations. Several of the five phases described in the GAO guide have been combined for this survey and an additional specific reference to contingency planning (business continuity contingency planning) has been added. The GAO guide describes the activities that should be undertaken in each phase of Y2K preparations and provides a detailed description of the components of each phase. A brief summary of each phase follows.

Instructions for Specific Survey Questions

Question 1

Response to Question 1 is intended to provide a summary statement regarding the status of each company's preparations to assure uninterrupted operation after December 31, 1999. Responses to items 1a through 1e are requested to provide a means of evaluating the status of the industry with regard to the key steps that have been characterized as constituting a Year 2000 preparation program.

Please check the entry that describes your company's situation in each of the five phases of Y2K preparations, which are described below, including dates where appropriate.

a. *Awareness and Assessment* - Definition of the problem, development of awareness within the organization, establishing a management process for the Y2K effort, developing a strategy, defining compliance, conducting an inventory of all systems and components, developing a plan for correcting non-compliant systems, developing a strategy for testing and validation, acquiring necessary resources and tools, and consideration of contingency plans.

b. *Renovation or Development of Alternative Solutions* - This includes all activities to renovate systems (conversion, replacement or retirement of systems) and to identify alternate procedures to be used in place of existing systems or practices. It includes monitoring, documentation, tracking and communication activities to manage the effort.

c. *Testing and Validation of Renovations, New Systems or Alternative Solutions* - This phase includes developing,

documenting and conducting all aspects of testing, including unit testing, integration testing, systems testing and acceptance testing, and recording and evaluating the results of all testing.

d. *Implementation of New Systems or Renovated Systems or Alternative Solutions* - This includes all activities associated with putting all new and converted systems into operation.

e. *Development of Contingency Plans* - This includes all activities to identify potential risks, from both internal or external systems failures, and to develop alternative plans, processes and operational methods to assure minimum adverse impact on continued business operations from these risks. Contingency plans should address all sources of potential risks and the means that will be used to ensure continuity of the core business processes.

Question 2

An independent review by a group or organization (whether internal or external to the firm) is an accepted practice to improve the quality of all critical functions, plans or operations. An external review can be used to provide increased confidence that a plan or process has been adequately conducted.

Questions 3 through 5 are self-explanatory.

Information regarding divisions and subsidiaries - If a division or subsidiary of a firm markets products under a trade or brand name(s) that is different from that of the parent company or if the division/subsidiary has registered with the Food and Drug Administration under a different corporate name or identity from the parent or controlling company, please provide the names of these divisions or subsidiaries, the trade names and the location of the division or subsidiary. This information will assist the FDA in determining whether all registered manufacturers have responded to the survey and will facilitate determination of the need for follow up.

If the Y2K readiness status of a division or subsidiary marketing products under a different trade name(s) from the parent or controlling firm is significantly different (either better or less well prepared for Y2K than the parent firm at this time), a separate survey response may be submitted for the division or subsidiary marketing products under the different name(s), provided this is clearly explained in the comment section. Otherwise, the Y2K readiness status of all divisions or subsidiaries is to be reflected in this survey response for the parent or owning firm. When divisions or subsidiaries marketing under different trade or brand names are included in the survey response, please identify the divisions and subsidiaries on the form provided for that purpose.

Submission of Survey - Responses to the survey should be mailed or faxed to the following address

Food and Drug Administration
Center for Devices and Radiological Health, HFZ-Y2K
Y2K Coordinator
9200 Corporate Boulevard
Rockville, Maryland 2080

FAX: 301-881-1848

For assistance in completing the survey or response to questions regarding the survey, please contact the contractor assisting the FDA with this effort at:

E-mail address: y2kstatus@bah.com
Telephone number: 1-877-744-1522 between 8:30 a.m. and 5:00 p.m. Monday through Friday, Eastern Time
Fax number for inquiries: 301-881-1848.